



## MID-TERM OUTCOME OF PULSTA NEW SELF-EXPANDABLE SYSTEM FOR PERCUTANEOUS PULMONARY VALVE IMPLANTATION IN THE NATIVE RIGHT VENTRICULAR OUTFLOW TRACT DYSFUNCTION IN A SINGLE CENTER

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### **Background:**

Percutaneous pulmonary valve implantation (PPVI) is a good treatment option for right ventricular outflow tract (RVOT) dysfunction. This study reports the clinical use in various morphology of RVOT and mid-term outcome of a novel transcatheter self-expandable pulmonary valve (Pulsta valve, Teawoong Medical Co, South Korea) in native RVOT dysfunction.

### **Objectives:**

A total of 43 patients who underwent PPVI with Pulsta valve in a single center from December 2017 to May 2022 were retrospectively and prospectively enrolled.

### **Methods:**

Patients' demographics and pre-procedural, intra-procedural, and short and mid-term follow-up data were collected and analyzed.

### **Results:**

The most of patients were female (n= 27, 63 %), with a mean age of  $27.0 \pm 9.1$  years (range: 12-61 years) and a mean weight  $61.0 \pm 14.8$  kg (range: 39.6 – 90.5 kg). 38 of 43 Patients showed moderate to severe PR, with a mean PR fraction derived cardiac MRI of  $40.7 \pm 9.9$  % (range: 23.0 – 63.0). The procedure success rate was 97.6 % with a mean fluoroscopy time of  $25.0 \pm 10.8$  min and mean procedure time of  $103.2 \pm 22.0$  min. Valve sizes used were 26 (n=3), 28 (n=13), 30 (n=7), 32 (n= 15), and 33.5 (n=5). Procedural complications were arrhythmia requiring treatment (n=2), delivery catheter associated complication (n=1), device embolization (n=1). 1-year follow-up cardiac MRI showed a decreased pulmonary regurgitation (PR) fraction ( $14.5 \pm 8.4$  %) and that the right ventricular end-diastolic volume index decreased from  $153.2 \pm 27.7$  to



120.3 ± 20.6 mL/m<sup>2</sup>, the right ventricular end-systolic volume index decreased from 81.3 ± 24.0 to 62.4 ± 15.6 mL/m<sup>2</sup>. After PPVI, NYHA functional class of patients improved to class 1 in most of patients' overtime. There was no significant PR and PS overtime. There was no mortality, or re-intervention during follow-up. And no patients had more than mild PR and paravalvular leakage.

**Conclusion:**

PULSTA valve provides excellent short and mid-term outcomes in patients with the various morphology of RVOT and special situation in high-risk patients.

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